



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Teknimed, S.A.
% Mr. J.D. Webb
President
OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

December 18, 2015

Re: K032685
Trade/Device Name: CEMSTOP Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: LZN
Dated: August 27, 2003
Received: August 29, 2003

Dear Mr. Webb:

This letter corrects our substantially equivalent letter of November 26, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

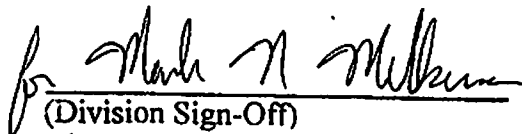
510(k) number (if known): K032685 10/1

Device Name: CEMSTOP Cement Restrictor

Indications for Use:

CEMSTOP Cement Restrictor
Indications for Use

The CEMSTOP Cement Restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during total hip arthroplasty. The CEMSTOP restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurization.



(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K032685

NOV 26 2003

510(k) Summary

K032685
1061

Date

August 27, 2003

Submitter

Teknimed, S.A.
11 rue Apollo
31240 L'Union
FRANCE

Contact person

J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name

Cement restrictor

Classification name

Cement obturator

Equivalent Device

Exactly the same as cleared on K993841 by Encore Medical. Equivalent to BIOSTOP (Landos) cleared on K943727.

Device Description

The CEMSTOP Cement Restrictor is inserted into the femoral canal prior to introduction of bone cement during total hip arthroplasty. It occludes the medullary canal and prevents the cement from flowing down the diaphysis and aids in cement pressurization. It is available in six sizes. It is fabricated from gelatin and glycerol and is completely resorbed within a few days of implantation. The gelatin is porcine based.

Intended Use

The CEMSTOP Cement Restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during total hip arthroplasty. The CEMSTOP restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurization.

Summary of Technological Characteristics Compared to Predicate Device

Design, manufacturing method and facilities, packaging and sterilization are performed by the same company as the Encore Medical device.

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